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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,505	01/15/2004	Caroline Delattre	016800-583	6320

21839 7590 04/06/2005

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,505	DELATTRE ET AL.	
	Examiner	Art Unit	
	Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1-26 and 28-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2-23-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed February 23, 2005, has been received and entered. Claims 1-32 are pending.

Election/Restrictions

Applicant's election with traverse of Group VI, claim 27 and new claim 32, in the reply filed on February 23, 2005, is acknowledged. The traversal is on the ground(s) that claims 22, 23, and 24 read on a regime or regimen very closely related to the regime or regimen of elected Group VI, as they are treating skin disorders related to lack of desquamation. This is not found persuasive because "skin disorder linked to desquamation" may not necessarily require promotion of desquamation, but rather the inhibition of desquamation. For instance, Nutrithys® cream for ultra-dry skin contains Cohesine® to combat desquamation. See http://www.sothys.com/EN/products_info.php?id=320. Furthermore, the skin disorders listed in claim 24 may not be linked to lack of desquamation, thus they may not be treated with a product that can promote desquamation. According to http://www.scalyskin.org/content.cfm?ContentID=179&ColumnID=4, "hyperkeratosis, in turn, can arise through either a delay in desquamation (shedding), and/or as a consequence of increased epidermal cell production (hyperplasia)...however, only in a few instances is the hyperkeratosis due solely to a failure to desquamate..." (page 1, second paragraph). Additionally, applicants allege that the promotion of desquamation would relate to the treatment of atopic dermatitis. However, symptoms of atopic dermatitis include increased desquamation, so it is not evident that promotion of desquamtion is desirable for the treatment of atopic

dermatitis (see page 285, first paragraph under "Clinical Features", Moreno Gimenez, Alergol Immunol Clin, 2000, 15: 279-295). In sum, it is maintained that the patient populations treated for each inventive group are different because they treat different diseases which exhibit different symptoms. Treatment of one disease may not render treatment of another disease obvious.

In addition, applicants assert that the compositions of Group I and the packages of Group IX are uniquely well suited for carrying out the regimes/regimens of the other inventive groups, including elected Group VI. However, Group I and Group IX comprise a modulator of the amidase activity of a hydrolase polypeptide, thus the modulator can be either an inhibitor or an activator of amidase activity. Additionally, the hydrolase as described may be used for the commercial production of a desired compound, such as L-ascorbic acid. Thus, the restriction requirement is maintained.

With respect, to the classification of certain inventive groups in the same class and subclass, note that the inventions have acquired a separate status in the art because of their recognized divergent subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-26 and 28-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 23, 2005.

Claims 27 and 32 are examined on the merits to the extent they read on the elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase, "precursor thereof", renders claims 27 and 32 indefinite because it is unclear what constitutes a precursor of hydrolase polypeptide. The degree of similarity with the hydrolase polypeptide encompassed in the phrase "precursor thereof" is not clear, therefore the term fails to delineate the scope of the ingredients encompassed. Thus claims 27 and 32 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27 and 32 are rejected under 35 U.S.C. 102(a) and/or 35 U.S.C 102(e) as being anticipated by Meyers (US 2002/0038014 A1) or Rudolph-Owen et al. (WO 03/038113 A2).

Meyers teaches novel asparaginases, 26443 and 4697 polypeptides, which hydrolyze asparagines to aspartic acid and ammonia (page 4, paragraph 0044) and serve as "therapeutic agents for controlling one or more of cellular proliferative and/or differentiative disorders" (page 4, paragraph 0046). Furthermore, 26443 and 4697 polypeptides and nucleic acids may be incorporated into pharmaceutical compositions wherein routes of administration include transdermal application (page 29, paragraph 0333). Additionally, the pharmaceutical compositions may include "citrates or phosphates and agents for the adjustment of tonicity" and agents for pH adjustment (page 29, paragraph 0333). These additional agents serve as enzyme activators, according to page 11, paragraph 0048 of the application under examination.

Rudolph-Owen et al. teaches the 25943 polypeptide, a glycosylasparaginase (page 18, lines 14-20). The 25943 polypeptide serves to modulate "cellular proliferation, growth, ..., differentiation, and/or migration" (page 20, lines 18-24). Furthermore, "25943 modulators identified according to the methods of the invention can be used to modulate cellular proliferation" (page 19, lines 10-11), and "can increase cellular proliferation by increasing 25943 activity in a subject" (page 19, lines 17-18). Moreover, the 25943 protein or a 25943 modulator may be administered to a subject in order to treat cellular proliferation disorder (page 44, lines 18-24). The incorporation of 25943 modulators in pharmaceutical compositions is disclosed (page 44, line 33 through page 45, line 22). In such as case, transdermal application is disclosed

as a route of administration (page 45, line 13). Finally, "citrates or phosphates and agents for the adjustment of tonicity", as well as acids or bases for pH adjustment may be included in the pharmaceutical composition (page 45, lines 19-21). These additional agents serve as enzyme activators, according to page 11, paragraph 0048 of the application under examination.

The polypeptides discussed above fit within the preferred embodiments discussed on pages 4 and 5 of the examined application. Both inventions modulate cellular proliferation and differentiation, thus they encompass modulation of skin hydration, cell renewal, and desquamation. A holding of anticipation is clearly required.

Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by van de Sandt et al. (In Vitro Cellular & Developmental Biology: Animal, 1995, 31(10): 761-766).

Van de Sandt et al. discloses the application of sodium dodecyl sulfate (SDS) on human skin. Their study demonstrated that certain concentrations of SDS cause increased cell proliferation. According to paragraph 0050 of the application under examination, SDS is an activator of a hydrolase polypeptide having amidase activity. A holding of anticipation is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan E. Fernandez
Art Unit 1651
Assistant Examiner

sef

FRANCISCO PRATS
PRIMARY EXAMINER